REMARKS

Reconsideration of the present application is respectfully requested. The arguments in the previous responses are maintained. Support for the new claims is found in the original claims and throughout the specification.

Claims 2-18, 22 and 64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Examiner states that a nucleic acid comprising a CycE polynucleotide having at least 80% identity to the entire coding region of SEQ ID NO:1 and complementary nucleotides thereof are not adequately described. The Examiner further states that it is unclear how the cyclin box and TTPXS structural element of a CycE polynucleotide relate to its function, or whether the structure and function of those elements would be preserved in and isolated nucleic acid having at least 80% identity to the entire coding region of SEQ ID NO:1. The Examiner goes on to say that it is unclear whether an isolated nucleic acid having at least 80% identity to the entire coding region of SEQ ID NO:1 would encode a polypeptide that binds to Cdk2.

Adequate written description of a claimed genus can be made via structure, formula, chemical name, or physical properties. *See Ex parte Maizel*, 27 USPQ2d 1662, 1669 (B.P.A.I. 1992), *citing Amgen v. Chugai*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). A genus of DNAs may therefore be described by means of a recitation of a representative number of DNAs, defined by nucleotide sequence, falling within the scope of the genus, or by means of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1569 (Fed. Cir. 1997); *see also* Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (2000).

In the present case, the claims recite a predictable structure having a high % sequence identity (e.g. 80%, 90%, or 95% as disclosed in the claims). In light of this extensive disclosure of structure, the requirement of adequate written description

has been met, and the rejection of the claims under 35 U.S.C. §112, first paragraph, should be withdrawn.

The written description requirement of 35 U.S.C. §112, first paragraph, may also be satisfied by a recitation of functional characteristics in the description, provided there is a correlation between the function and structure of the claimed invention. *Id.*, *citing Lilly* at 1568.

Example 14 of the *Revised Interim Written Description Guidelines* (available at www.uspto.gov/web/menu/written.pdf, page 53), for example, is directed to a generic claim of a protein having high sequence identity to the sequence of SEQ ID NO:3, *wherein the sequence catalyzes the reaction A→B.* The *Guidelines* concludes that the generic claim of Example 14 is sufficiently described under § 112, first paragraph, because 1) "the single sequence disclosed in SEQ ID NO:3 is representative of the genus" and 2) the claim recites a limitation requiring the compound to catalyze the reaction from A→B. Thus, on the basis of the limitations provided in Example 14, one of skill in art would recognize that the patentee was in possession of the necessary common attributes possessed by the members of the genus, in satisfaction of the written description requirements.

In the present case, all claims have been drafted with the functional limitation that the nucleotide sequences claimed require Cyclin E activity or are capable of modulating the level of Cyclin E protein in a cell. Support for which may be found in the original claims, throughout the specification, and in the Examples in particular. Consequently these claims are in the same form as that provided in Example 14 of the Guidelines discussed above and, as such, satisfy the written description requirement. Thus the rejection of the claims under 35 U.S.C. §112, first paragraph, should be withdrawn.

Claims 2-25 and 27-53, and claim 64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and /or use the invention.

The Examiner maintains that the scope of the invention is not enabled. The Examiner states that the specification does not reasonably provide enablement for a CycE polynucleotide having at least 80% identity to the entire coding region of SEQ ID NO:1 and complementary nucleotides thereof. The Examiner concludes that the scope of the invention is not enabled because of the unpredictability of determining the function of isolated nucleic acids homologous to SEQ ID NO:1, and because of the unpredictability of altering the phenotype of a plant by transforming it with isolated nucleic acids homologous to SEQ ID NO:1.

As detailed above, the specification provides not only the full-length polynucleotide sequences of the present invention, but also guidance on modifications and variants as well as methods to identify compositions and assays to determine their functionality. Although assaying will be required to identify candidates, this does not mean the invention is not enabled. Further, using only the degeneracy of the genetic code, one could produce a polynucleotide of only approximately less than 80% sequence identity to the sequences claimed without changing the amino acid sequence of the encoded polypeptide. The references will be discussed below in the context in which they were cited regarding scope of enablement.

Thus, the Applicant respectfully submits that the specification describes the invention in sufficient detail to reasonably convey the scope of the invention. As discussed in previous responses, the testing to determine functionality is routine.

Original claims 3, 5, 12, and 14-17 remain rejected, newly added claim 64 is rejected, and newly amended claims 2, 4, 6-11, 13, 18, and 22 are rejected under 35 USC 101 as not being supported by a specific and substantial utility, for the reasons of record set forth in the previous office action. The Examiner maintains that the invention does not have a specific and substantial utility because it is unclear whether the expression of a functional CycE nucleic acid in a host cell would result in an increase in the G1 to S transition of the host cell, or an increase in transformation efficiency of the host cell.

Demonstration of function and utility is found in the 1.132 Declaration submitted June 28, 2001. The Examiner's attention is directed to page 2 of the Declaration.

"Function of G1 cyclins (Cyclin D and E) is demonstrated though replacement or complementation of mutant yeast strains. Thus, cloning of a non-yeast cyclin gene into a yeast expression cassette and transformation of the G1-cyclin-deficient yeast strain will demonstrate whether the non-yeast cyclin gene functions in promoting G1/S transition. Cyclin A & B are mitotic cyclins and will not complement G1-cyclin-deficient yeast. This assay has been used to verify function (stimulating progression from G1 to S phase) for cyclin-D genes from various mammalian species, Drosophila, Arabidopsis, tobacco and other plants including maize (Figure 2). Likewise, Cyclin E genes from mammalian cells and Drosophila are known to stimulate this cell cycle transition and permit growth in the mutant yeast strain (Figure 2). As with the maize CycD, our putative CycE gene complements the G1-cyclin-deficient yeast. This functionally verifies that this gene is a G1-cyclin (Cyclin D or E) (References 2 and 3)."

Figure 2 of the Declaration clearly demonstrates healthy colonies of yeast cells. Colonies of mutant yeast cells would not proliferate in the absence of a transformed cyclin gene.

Withdrawal of the rejection of claims 18 and 19 under 35 USC 101 as being directed to non-statutory subject matter is noted with appreciation.

Withdrawal of the rejection of claims 1-12 under 35 USC 102(b) as being anticipated by Kende *et al.* is noted with appreciation.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

In view of the above amendments and comments withdrawal of the outstanding rejections and allowance of all of the remaining claims is respectfully requested.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claim 64 has been amended as follows:

64. (Amended) An isolated ~~Cyclin E~~ nucleic acid capable of modulating the level of Cyclin E protein, wherein the nucleic acid comprises ~~comprising~~ a member selected from the group consisting of:
    (a) a polynucleotide that encodes a polypeptide of SEQ ID NO: 2;
    (b) a plant Cyclin E polynucleotide having at least 80~~70~~% identity to the entire coding region of SEQ ID NO: 1, wherein the % identity is determined by GCG/bestfit GAP 10 program using a gap creation penalty of 50 and a gap extension penalty of 3;
    (c) a polynucleotide having the sequence set forth in SEQ ID NO: 1; and
    (d) a polynucleotide fully complementary to a polynucleotide of (a) through (c).

New claims 65-75 have been added as follows:

65. An isolated nucleic acid encoding a protein having Cyclin E activity, wherein the nucleic acid comprises a polynucleotide that encodes a polypeptide of SEQ ID NO: 2.

66. An isolated nucleic acid capable of modulating the level of Cyclin E protein in a cell, wherein the nucleic acid comprises a polynucleotide having at least 80% identity to the entire coding region of SEQ ID NO: 1, wherein the % identity is determined by GCG/bestfit GAP 10 program using default parameters.

67. The isolated nucleic acid of claim 66, wherein the polynucleotide has at least 85% identity.

68. The isolated nucleic acid of claim 67, wherein the polynucleotide has at least 90% identity.

69. The isolated nucleic acid of claim 68, wherein the polynucleotide has at least 95% identity.

70. An isolated nucleic acid capable of modulating the level of Cyclin E protein in a cell, wherein the nucleic acid comprises a polynucleotide having the sequence set forth in SEQ ID NO: 1.

71. An isolated nucleic acid capable of modulating the level of Cyclin E protein in a cell, wherein the nucleic acid comprises a polynucleotide fully complementary to at least 80% of the entire coding region of SEQ ID NO: 1, wherein the % identity is determined by GCG/bestfit GAP 10 program using default parameters.

72. The isolated nucleic acid of claim 71, wherein the polynucleotide has at least 85% identity.

73. The isolated nucleic acid of claim 72, wherein the polynucleotide has at least 90% identity.

74. The isolated nucleic acid of claim 73, wherein the polynucleotide has at least 95% identity.

75. An isolated nucleic acid capable of modulating the level of Cyclin E protein in a cell, wherein the nucleic acid comprises a polynucleotide fully complementary to the sequence set forth in SEQ ID NO: 1.